UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,882	03/11/2002	Richard William Titball	41577/270459	2737

7590 08/08/2006

John S Pratt
Kilpatrich Stockton
Suite 2800
1100 Peachtree Street
Atlanta, GA 30309-4530

EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,882	TITBALL ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 23-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 23-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

1) Acknowledgment is made of Applicants' amendments filed 05/23/06 in response to the non-final Office Action mailed 02/23/06. With this, Applicants have amended the specification and the claims.

Status of Claims

2) Claims 1, 23-25, 27 and 30 have been amended via the amendment filed 05/23/06.

Claims 2-4, 7-15 and 17-22 have been canceled via the amendment filed 05/23/06.

Claims 1 and 23-32 are pending and are under examination.

Objection(s) Maintained

3) The objection to the specification made in paragraph 3(A)(a) of the Office Action mailed 02/23/06 is maintained for reasons set forth therein and herebelow.

Although Applicants have amended lines 6-11 of page 4 of the instant specification, the amendment makes no sense. The specification still lacks proper antecedent basis. See new objection to the specification set forth below.

Objection(s) to Specification

4) The specification is objected to for the following reason(s):

The amendment introduced to lines 6-11 of page 4 of the specification via the amendment filed 05/23/06 renders the specification incorrect and/or confusing. The specification as amended is further objected to under 35 U.S.C. § 132, because it introduces new matter into the disclosure. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. Applicants are required to cancel the new matter in the response to this Office Action. The amendment introduced to lines 6-11 of page 4 of the specification via the amendment filed 05/23/06 is reproduced below:

> Thus, the present invention provides a method of enhancing expression of a nucleic acid encoding a desired protein at mucosal effector sites, said method comprising placing the protein to be expressed under the control of a promoter having SEQ ID NO: 2, SEQ ID NO: 3 or SEQ ID NO: 4 or a fragment or variant or any of these which has promoter activity, and causing expression in mucosal cells.

The method originally described in the instant specification is a method of expression of a desired protein at mucosal effector sites, but not a method of expression of 'a nucleic acid encoding a' desired protein. The now recited method in this part of the specification constitutes new matter. To obviate the objection, it is suggested that Applicants remove the above-identified added limitation -- a nucleic acid encoding-- and insert it after the limitation 'comprising placing'.

Objection(s) Withdrawn

5) The objection to the specification made in paragraph 3(B) of the Office Action mailed 02/23/06 is withdrawn in light of Applicants' amendment to the specification.

6) The objection to the specification made in paragraph 3(A)(b) of the Office Action mailed 02/23/06 is withdrawn.

Rejection(s) Moot

7) The rejection of claims 2-4, 7-15, 17-19, 21 and 22 made in paragraph 13 of the Office Action mailed 03/23/05 and maintained in paragraph 27 of the Office Action mailed 02/23/06 under 35 U.S.C § 102(e) as being anticipated by Titball *et al.* (US 5,985,285, filed 09/15/1997) ('285), is moot in light of Applicants' cancellation of the claims.

8) The rejection of claims 2-4, 7-15, 17-19, 21 and 22 made in paragraph 14 of the Office Action mailed 03/23/05 and maintained in paragraph 28 of the Office Action mailed 02/23/06 under 35 U.S.C § 102(b) as being anticipated by Titball *et al.* (WO 96/28551 – Applicants' IDS) ('551), is moot in light of Applicants' cancellation of the claims.

9) The rejection of claim 2 made in paragraph 30(b) of the Office Action mailed 02/23/06 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

10) The rejection of claims 11 and 22 made in paragraph 30(d) of the Office Action mailed 02/23/06 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

11) The rejection of claim 20 made in paragraph 30(h) of the Office Action mailed 02/23/06 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

12) The rejection of claims 3, 4, 7-15 and 17-22 made in paragraph 30(j) of the Office Action mailed 02/23/06 under 35 U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

Rejection(s) Withdrawn

13) The rejection of claims 23-32 in paragraph 29 of the Office Action mailed 02/23/06 under 35 U.S.C § 112, first paragraph, as containing new matter, is withdrawn. A new rejection as necessitated by Applicants' amendments to the claims is set forth below.

14) The rejection of claim 1 made in paragraph 30(a) of the Office Action mailed 02/23/06 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim. A new rejection as necessitated by Applicants' amendment to the claim is set forth below.

15) The rejection of claim 23 made in paragraph 30(c) of the Office Action mailed 02/23/06 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

16) The rejection of claim 30 made in paragraph 30(d) of the Office Action mailed 02/23/06 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

17) The rejection of claim 23 made in paragraph 30(e) of the Office Action mailed 02/23/06 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

18) The rejection of claim 24 made in paragraph 30(f) of the Office Action mailed 02/23/06 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

19) The rejection of claim 1 made in paragraph 30(g) of the Office Action mailed 02/23/06 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

20) The rejection of claim 27 made in paragraph 30(i) of the Office Action mailed 02/23/06

under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

21) The rejection of claims 23-32, 27 made in paragraph 30(j) of the Office Action mailed 02/23/06 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.

New Rejection(s) Necessitated by Applicants' Amendment

The new rejections set forth below are necessitated by Applicants' amendments to the claims. The claims are so poorly presented that the metes and bounds or the scope of the claims cannot be determined currently.

Rejection(s) under 35 U.S.C § 112, First Paragraph (New Matter)

22) Claims 1, 23, 24 and those dependent therefrom are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1, as amended currently, includes the new limitations: 'the nucleotide sequence of SEQ ID NO: 2 in a construct, which is administered to mucosal cells'. Claim 23, as amended, includes the limitations: 'desired protein induces' a protective immune response against a pathogen in a mammal to which 'the protein' is administered. Claim 24 depends from claim 1, and as amended currently, includes the new limitations: 'construct is transformed into' a recombinant gut-colonising microorganism. The instant specification, as originally filed, does not provide descriptive support for the now claimed method of claim 1, i.e., a method of enhancing expression of a desired protein at mucosal effector sites, which includes the step of placing the recited nucleotide sequence 'in a construct', and the step of administering which to mucosal cells. The original claim 1 and the description at lines 6-11 on page 4 of the specification, do not describe a method of enhancing expression of a desired protein at mucosal effector sites as recited, wherein a construct 'is administered to mucosal cells'; or such a method wherein 'the desired protein' is administered to a mammal (claim 23) in addition to administering a construct to mucosal cells; and such a method that includes administration of a construct to mucosal cells and which further includes transformation of the construct into a recombinant gut-colonising microorganism.

Therefore, the above-identified limitations in the claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to remove the new matter from the claim(s), or invited to point to specific pages and line numbers in the originally filed specification where support for recitations can be found.

Rejection(s) under 35 U.S.C § 112, Second Paragraph

23) Claims 1 and 23-32 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 1 is vague, confusing and indefinite in the limitations: 'enhancing expression of a desired protein at mucosal effector sites ..... comprising placing a nucleotide sequence ..... under the control of a promoter .... in a construct ' and 'which is administered to mucosal cells'. First, it is unclear what exactly is administered to mucosal cells: 'construct' or the expressed 'protein'? Second, it is unclear how is the administration to mucosal cells achieved: by injection into the cells, *in vitro*, *in vivo*? Is the method claimed in claim 1 an *in vitro* method wherein the step of placing a nucleotide encoding the protein under the control of the recited promoter and the step of administering to mucosal cells occur *in vitro*? Or are the two steps taking place *in vivo*? Clarification/correction is requested.

(b) Claims 23 and 1 are very confusing and are inconsistent with regard to the scope. Claim 23 depends from claim 1. From the limitation in the dependent claim 23: 'a mammal to which the protein is administered', and the limitation from the base claim 1: 'is administered to mucosal cells', it is unclear how many steps of administration are involved in the method of claim 23, and how many products are administered. It is further unclear how the step from claim 1 of placing a nucleotide sequence encoding a generic 'desired protein' under the control of the recited promoter in a construct permits one to 'administer the protein' to a mammal in claim 23 such that the generically recited desired protein induces a protective immune response specific to a

pathogen. What is the source of the 'mucosal cells' in claim 1 to which a construct is administered? Are these mucosal cells part of a mammal, or are these mucosal cells isolated cells present for example in a Petri dish? Is there a connection between 'mucosal cells' of claim 1 to which is the construct administered in claim 1 and 'a mammal' of claim 23 to which the desired protein is administered. The contents of the claims make no sense.

(c) Claim 24 is indefinite and confusing in the limitation: 'method of claim 1, wherein the construct is transformed into a recombinant gut-colonising microorganism'. Claim 24 depends from claim 1, which recites that 'a construct' is administered to mucosal cells. However, the dependent claim 24 recites that 'the construct' from claim 1 is 'transformed into a recombinant gut-colonising microorganism'. Is the transformation of the construct into a recombinant gut-colonising microorganism taking place in the mucosal cells to which the construct is administered? As presented currently, the scope of the claim cannot be determined.

(d) Claim 29 is indefinite and confusing in the limitation: 'method of claim 23, wherein the protein is able to induce a protective immune response against *Yersinia pestis*'. Claim 29 depends from claim 23, wherein 'the desired protein induces a protective immune response against a pathogen in a mammal to which the protein is administered'. Is this the same 'desired protein' from claim 23 that is able to induce an additional protective immune response against *Yersinia pestis* in the method claimed in claim 29?

(e) Claims 31 and 32 are indefinite and confusing. Claim 31 is indefinite and confusing in the limitation: 'method of claim 24, wherein the recombinant gut-colonising is administered as a composition which further comprises a pharmaceutically acceptable carrier'. Claim 31 depends from claim 24, which is a method claim (as opposed to a composition claim) which does not include any 'administering' step. Claim 24 depends from claim 1 which includes 'administering' to mucosal cells. To whom or what the recombinant gut-colonising microorganism of claim 31 is administered to as a composition? Is the recombinant gut-colonising microorganism of claim 31 administered as a composition to the mucosal cells recited in claim 1 which have already been administered with a construct? Claim 31 and its dependent claim 32 make absolutely no sense.

(f) Claims 23-32, which depend directly or indirectly from claim 1, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Remarks

24) Claims 1 and 23-32 stand rejected.

25) Applicants' amendments necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

26) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission.. Papers should be transmitted via the PTO Fax number (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

27) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

28) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached

on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

August, 2006

S. DEVI, PH.D.
PRIMARY EXAMINER